NICE National Institute for Health and Care Excellence

NICE guidance

Endovascular closure of patent ductus arteriosus

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG97.

1 Recommendations

1.1 Current evidence on the safety and efficacy of endovascular closure of patent ductus arteriosus (PDA) appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications.

1.3 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into this database.

2 The procedure

2.1 Indications

2.1.1 The ductus arteriosus is a normal vessel in the fetus that connects the pulmonary artery and the aorta. It allows the fetal blood flow to bypass the lungs, which are not used in utero. The ductus arteriosus usually closes at or shortly after birth. Sometimes it fails to close on its own; this is called a patent (or persistent) ductus arteriosus. Blood can then pass from the aorta into the pulmonary artery, exposing the lungs to increased blood flow and pressure. A large patent ductus arteriosus (PDA) may cause symptoms such as poor weight gain and breathlessness. Without medical treatment, blood vessels in the lung may eventually become damaged by the raised blood pressure. This puts strain on the heart and can lead to heart failure. Persistent ductus arteriosus is also associated with an increased risk of endocarditis, a life-threatening infection of the lining of the heart chambers and valves.

2.1.2 Open surgery is the standard treatment. Access to the heart is gained via an incision in the chest and a stitch and/or clip is placed around both ends of the ductus arteriosus (ligation), which is then cut in half if there is enough length (ligation and division).

2.2 Outline of the procedure

2.2.1 The endovascular procedure involves passing a catheter through a vein or artery into the heart. Pressure measurements and angiograms may be performed to assess the size and shape of the ductus. An occlusion device is then introduced into the ductus through the catheter under X-ray guidance. The choice of device depends largely on the size of the PDA. Coils are suitable for closing PDAs of small to moderate size. Other occlusion devices are used to close larger PDAs. Small residual shunts after the procedure often resolve as endothelial tissue grows over and around the device.

2.3 Efficacy

2.3.1 Three non-randomised controlled studies reported efficacy data. In 2 of them, immediate occlusion was reported in 68% (71 out of 105) and 77% (23 out of 30) of patients treated with endovascular closure, and in 89% (8 out of 9) and 96% (140 out of 146) of patients treated with open surgery. The third study reported that 94% (93 out of 99) of patients treated with endovascular closure had a successful outcome immediately after the procedure, compared with 99% (109 out of 110) of patients treated with open surgery. The 4 case series, with a total of 2,035 patients, reported rates of immediate complete occlusion between 44% (90 out of 205) and 98% (214 out of 218) following endovascular closure. In all studies, occlusion rates after a period of follow-up were higher than immediately after the procedure. In 1 case series of 1,258 patients, the occlusion rate was 96% at 2-year follow-up compared with an immediate occlusion rate of 59%. For more details, see the overview.

2.3.2 The Specialist Advisors noted that a small proportion of patients would have a residual shunt.

2.4 Safety

2.4.1 The most commonly reported complications were haemolysis (most commonly mild to moderate) and embolisation of the device. Rates of haemolysis varied from 0.3% (1 out of 316) to 9% (3 out of 34), and rates of embolisation varied from 0.6% (2 out of 316) to 7% (7 out of 105). A study of 316 patients reported 1 death as a result of the procedure. For more details, see the overview.

2.4.2 The Specialist Advisors considered that device embolisation, haemolysis, vascular injury and death were potential adverse events.

2.5 Other comments

2.5.1 There is a potential for long-term adverse effects and clinicians should report these to the Medicines and Healthcare products Regulatory Agency (MHRA).

2.5.2 These recommendations were based on evidence on the use of the Amplatzer device and coil embolisation for patent (or persistent) ductus arteriosus. The Institute may review the procedure if further data relating to other devices become available.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 97 has been migrated to HealthTech guidance 59. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.